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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,893	10/27/2000	Morey Kraus	07588-008001	5973

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EXAMINER
FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	17

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/698,893	KRAUS ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-25,27,29-37 and 40-47* is/are pending in the application.

4a) Of the above claim(s) *12,22-24,42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-17,19-21,25,27,29-37,40,41 and 44-46* is/are rejected.

7)☒ Claim(s) *47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed April 18, 2003 (Paper No. 13) has been entered. Claims 1 and 37 have been amended. Claims 18, 26, 28, 38, and 39 have been cancelled. Claims 44-47 have been newly added.

Claims 1-17, 19-25, 27, 29-37, and 40-47 are pending in the instant application.

Claims 12, 22-24, 42, and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction requirement in Paper No. 8.

Accordingly, Claims 1-11, 13-17, 19-21, 25, 27, 29-37, 40, 41, and 44-47 are examined herein.

Claims 1-11, 13-17, 19-21, 25, 27, 29-37, 40, and 41 encompass non-elected subject matter. The elected invention is drawm to a method of treating stroke. Thus, Claims 1-11, 13-17, 25, 27, 29-37, 40, and 41 are examined herein only to the extent that they encompass the elected subject matter.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Newly added Claim 45 includes new matter

Claim 45 recites intravenous administration. However, there is no support in the original disclosure for intravenous administration of cells. At page 4, lines 4-5, the original disclosure contemplates intercerebral administration. At page 6, lines 1-3, the specification contemplates intracerebral injection, either directly into the brain (intraparenchymally) or into the spinal fluid (intraventricularly or intracisternally). Although the specification contemplates intravenous administration of growth factors (p. 9, lines 4-6), it does not contemplate intravenous administration of the cells.

Applicants have not pointed to specific support for this amendment in the specification as-filed and the Examiner has carefully reviewed the entire specification and does not find specific support for this amendment.

Enablement

Claims 1-11, 13-17, 19-21, 25, 27, 29-37, 40, and 41 stand rejected and Claims 44-46 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 3-6 of the Office Action of Paper No. 9 (mailed 12/18/02), because the specification, while being enabling for a method of causing improvement in function of the central nervous system in a mammal having a brain ischemia resulting from stroke, comprising injecting CD34+/-, Lin- cells into an ischemic region of the mammal's brain, does not reasonably provide enablement for the various methods of treating covered by the claims. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At pages 5-6 of the response, Applicants argue that the specification is broadly enabling for administration of a variety of cell types including stem cells as recited in Claim 2 and dependent claims. Applicants argue that, at the time of filing the application, stem cells "were well characterized in hundreds of scientific articles and numerous patents." However, the issue is not whether certain stem cells were well characterized, but whether the skilled artisan would know which stem cells would be useful in the claimed method and produce the claimed effect. As discussed in the previous Office Action, the state of the art is such that very little is known about the cell types that can be used to restore neurological function. One of the lingering questions in the field of stem cell research relates to the stage of differentiation of stem cells useful for transplantation and whether the same stage will be useful for all transplantation applications, or vary on a case-by-case basis (see p. ES-8, column 1 of Stem Cells: Scientific Progress and Future Research Directions, June 2001).

At page 7 of the response, Applicants argue that other modes of administration are listed in the specification. Further, Applicants point to the Declaration of Dr. Finkelstein which discloses that intravenous administration of umbilical cord blood cells resulted in functional improvement in a rat stroke model. The Declaration of Dr. Finkelstein has been fully considered and the Examiner accepts that the example described therein demonstrates that intravenous administration of umbilical cord blood cells in combination with a growth factor did result in functional improvement. However, for the reasons discussed herein above with regard to the new matter rejection, the specification does not contemplate intravenous administration.

Thus, the rejection is maintained for reasons of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13-17, 19-21, 25, 27, 29-37, 40, 41, 45, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11, 13-17, 19-21, 25, 27, 29-37, 40, and 41 remain indefinite because the claims are directed to treating any disorder of the central nervous system, but the elected invention is limited to methods of treating stroke. Thus, the metes and bounds of the claims are not clearly set forth.

At page 4 of the response, Applicants argue that the claim language is definite and that the restriction requirement was traversed. However, the metes and bounds of the claims are not clearly set forth and do not reflect the elected invention. The restriction requirement has already been made final. Applicants may petition the restriction requirement under 37 CFR 1.144.

Claims 2-11, 13-17, 19-21, 25, 27, 29-37, 40, and 41 remain indefinite and newly added Claims 45 and 46 are indefinite in their recitation of "causing an improvement in function of the central nervous system" in the preamble of the claims because there is no step where said "improvement" is effected.

At page 4 of the response, Applicants argue that this ground of rejection has been overcome by the amendment to Claim 1. However, independent Claims 2, 3, and 37, as well as the claims depending therefrom, have not been amended in similar fashion, and therefore remain rejected.

Claim 27 is indefinite because it depends from cancelled Claim 26.

Claim 39 is indefinite in its recitation of "wherein the starting sample is cord blood or is derived from cord blood" because Claim 37 is already limited to "a starting sample of cord blood cells."

Allowable Subject Matter

Claim 47 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowable.

This application contains claims 12, 22-24, 42, and 43 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER